

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the DYNASTY® Acetabular System with Ceramic.

Submitted By: MicroPort Orthopedics Inc.
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Date: April 4, 2014

Contact Person: Matt Paul
Project Manager, Regulatory Affairs

Proprietary Name: DYNASTY® Acetabular System with Ceramic

Common Name: Acetabular Shell, Acetabular Liner, Femoral Head

Classification Name and Reference: 888.3353 prosthesis, hip, semi-constrained,
metal/ceramic/polymer, cemented or non-porous,
uncemented Class II

Subject Product Code and Panel Code: Orthopedics/87/LZO

Predicate Devices: DYNASTY® Acetabular System with Ceramic
510(k): K130376
Shell: K002149; Liner: K052026; Head: K130376

DEVICE INFORMATION

A. Intended Use

MicroPort total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty. Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

B. Device Description

The DYNASTY® Acetabular System with Ceramic contains femoral heads in size 28mm manufactured from alumina matrix composite, mating acetabular liners manufactured from crosslinked polyethylene, and beaded acetabular shells manufactured from titanium alloy.

C. Substantial Equivalence Information

The subject DYNASTY® Acetabular System with Ceramic is indicated to be paired with the following existing acetabular components summarized in Table 1. These shell types were cleared in K130376 for use with larger diameter BIOLOX® DELTA ceramic-polyethylene bearings.

Table 1. Compatible Shells, Including 510(k) Information. All shells were cleared for use with BioloX Delta heads and polyethylene liners in K130376.

510(k)	Device Name
K122382	DYNASTY® 10 Hole Revision Shells
K122382	DYNASTY® BIOFOAM® 3-Hole Shells
K122382	DYNASTY® BIOFOAM® Solid Shells
K122382	DYNASTY® BIOFOAM® 5 Hole Shells
K082924	DYNASTY® BIOFOAM® Shells

The subject DYNASTY® Acetabular System with Ceramic is indicated to be paired with the following femoral components summarized in Table 2.

Table 2. Compatible Femoral Components, Including 510(k) Information. All femoral stems were cleared for use with BioloX Delta heads in K130376, except K130984.

510(k)	Device Name
K003016	PRO-FEMUR R
K012091	PRO-FEMUR
K021346	STEM HIP REPLACEMENT SYSTEM
K041114	PROFEMUR TAPERED HIP STEM
K041586	PROFEMUR S HIP STEM
K051995	PROFEMUR RENAISSANCE HIP STEM
K052915	PROFEMUR XTR HIP STEM
K053588	PROFEMUR LX HIP STEM
K060358	PROFEMUR TL HIP STEM
K080663	PROFEMUR LX REVISION 5/8 COATED HIP STEM
K081090	PROFEMUR LX 5/8 COATED HIP STEM
K091423 K100866	PROFEMUR HIP SYSTEM MODULAR NECKS
K110399	GLADIATOR PLASMA CLASSIC HIP STEM
K111698	PROFEMUR(R) E CEMENTLESS HIP STEM
K111699	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM
K111910	GLADIATOR HIP STEM
K112080	PRESERVE HIP STEM
K112150	PROFEMUR GLADIATOR HA HIP STEM
K121221	PROFEMUR Z REVISION HIP STEM
K123434	PROFEMUR Z CLASSIC STEM
K123688	PROFEMUR TL CLASSIC STEM
K130984	PROFEMUR RENAISSANCE CLASSIC STEM

The design features of the subject femoral head devices are substantially equivalent to those of the predicate DYNASTY® Acetabular system devices cleared under K130376. The design features of the subject acetabular liner and shell devices are substantially equivalent to those of the predicate LINEAGE® Acetabular system devices cleared under K052026 and K002149. The indications of the subject device are identical to the predicate. Specific warnings are added in the package insert. The fundamental scientific technology of the modified devices has not changed relative to the predicate

devices. Validation of sterilization residuals by ethylene oxide was conducted on devices cleared in K893685 and K002149; this validation was submitted in K130376, is applicable to the subject devices and is included again in this notification. The safety and effectiveness of the DYNASTY® Acetabular System with Ceramic is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

D. Nonclinical Testing

The subject DYNASTY® Acetabular System with Ceramic was evaluated mechanically and tribologically. The mechanical testing on the subject and predicate devices was performed on wrought Cobalt Chrome modular neck spigots cleared under K091423 and K100866. The subject size 28mm ceramic head was used as a worst case in burst, post-fatigue burst, rotational stability, and pull off force testing. Wear testing compared the subject size 28mm femoral heads to the K130376 DYNASTY® Acetabular System. Range of motion evaluation compared the subject system to the predicate K052026 in three planes.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Conclusion

The design features of the subject devices are substantially equivalent to the predicate devices. The instrument list and materials remain identical to those cleared under K122382 and K130376. The safety and effectiveness of the DYNASTY® Acetabular System with Ceramic is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

MicroPort Orthopedics, Inc.
Max Mortensen, Ph.D.
VP Global Quality Systems, Regulatory and Clinical Affairs,
Reimbursement and Market Access
5677 Airline Road
Arlington, Tennessee 38002

Re: K140043

Trade/Device Name: Dynasty Acetabular System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or
nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: December 17, 2013
Received: January 8, 2014

Dear Dr. Mortensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140043

Device Name

Dynasty Acetabular System

Indications for Use (Describe)

The DYNASTY® Acetabular System is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth Frank -S

Division of Orthopedic Devices